UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER	
WITZ, J	
ART UNIT	**PAPER NUMBER**
1808	8

DATE MAILED: 08/26/96

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

☐ is extended to run _____ from the date of the Final Rejection

☒ continues to run 3 mos from the date of the Final Rejection

☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date that the shortened statutory period for response expires as set forth above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 8/5/96 has been considered with the following affect, but it is not deemed to place the application in condition for allowance:

1. ☒ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
   b. ☒ They raise new issues that would require further consideration and/or search. (See Note).
   c. ☐ They raise the issue of new matter. (See Note).
   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: Issues of degree of reduction of adipose tissue by 25-75% would require further search + consideration.

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing of an appeal, the proposed amendment ☐ will be ☒ will not be, entered and the status of the claims in this application would be as follows:

   Allowed claims: NONE
   Claims objected to: NONE
   Claims rejected: 1-18

   However;

   a. ☐ The rejection of claims _____ on references is deemed to be overcome by applicant's response.
   b. ☒ The rejection of claims 1-18 on non-reference grounds only is deemed to be overcome by applicant's response.

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

DETAILED ACTION

Response to Amendment

1. The amendment filed August 5, 1996 pursuant to 37 CFR 1.116 has not been entered. Applicant's arguments filed August 5, 1996 have been fully considered with the following results.

Applicant's arguments with regard to the rejection of record under 35 USC 112, 1st paragraph, lack of enablement, have been found to be persuasive and said rejection has been withdrawn.

Applicant's arguments with regard to the rejection of record under 35 USC 103 have not been found to be persuasive for the reasons set forth below. Applicant argues that, because Lee treats liposuctioned fat in vitro, the reference fails to teach that collagenase may be used in vivo to digest adipose tissue by stating that Lee et al. "specif[ies] eight different bodily conditions that can be treated with their enzyme compositions . . . . [y]et subcutaneous fat, or fat of any kind, is not mentioned."

The Examiner notes several points. First, the disclosure of the patent is drawn to proteolytic enzyme composition containing collagenase "useful for hydrolyzing connective tissue in biological systems." See col. 3, lines 60-65. Further, at col. 5, lines 20-33, the patent states that "the teachings of the present invention [are] widely applicable in a number of tissue digestion procedures including those which involve in vivo digestion . . . ." While it is clear that the in vivo digestion of adipose tissue was not expressly disclosed (the rejection was made under 35

USC 103, not 35 USC 102), the teaching of a U.S. patent is not limited to its preferred embodiments. The prior art shows that connective tissue, including adipose tissue, may be digested by use of a collagenase-containing proteolytic composition and that such composition is conventionally administered in vivo for the exact purpose of dissolving a broad range of different types of connective tissue. Second, as per Applicant's own statements, all that is required of the claimed method is that adipose tissue is reduced at a selected site. The term "tissue" is defined as "an aggregation of morphologically and functionally similar cells" and "cellular matter regarded as a collective entity." As a result of disaggregation of these cells by dissolution of the connective tissue matrix, the tissue has been digested and therefore its amount has been reduced. Such is clearly taught as predictable from the teaching of Lee et al. such that one of ordinary skill in the art would expect that, should he/she wish to reduce the amount of any connective tissue, including adipose tissue, at a site in the body, one would be motivated to use a composition well known to digest said tissue with a reasonable expectation of success. Applicant's arguments regarding the lack of in vivo teaching for the use of the proteolytic compositions on adipose tissue are not persuasive as it is noted that absolute predictability is not required under the standard of obviousness of 35 USC 103; all that is required is a reasonable expectation of success. In re Long, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). As stated before, as Applicant has repeatedly pointed out, all that it required of the claims is that adipose tissue at a selected site is reduced. The practitioner would clearly be motivated to apply the compositions of Lee et al. to

adipose tissue, either in vivo or in vitro, as the reference teaches that these compositions will act to digest adipose tissue.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073.

Jean C. Witz
Patent Examiner, Group 1800

August 21, 1996